



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SP 99P-5329/CP 1

March 20, 2000

Mark L. Shepard, M.S.
Vice President
Shotwell & Carr, Inc.
3535 Firewheel Dr., Suite A
Flower Mound, TX 75028-2628

Dear Mr. Shepard:

We refer to your suitability petition filed December 3, 1999, on behalf of Tyler Group, Inc., in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a dosage form that differs from that of an approved new animal drug. The proposed pioneer product is Hoechst Roussel Vet's Lasix® Tablets (furosemide tablets) which is intended for use in dogs and cats (NADA 34-621).

Your proposed product differs from the pioneer product in dosage form and therefore delivery method. The pioneer product is a tablet containing 12.5 mg furosemide; whereas your proposed product is a palatable, chewable tablet containing 12.5 mg furosemide. The dosage of active ingredient per pound of body weight will be the same.

Change in dosage form is one of the five variances in the pioneer product which can be considered through a suitability petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. We are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed generic product.

Your suitability petition is approved. Approval of the suitability petition does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA.

In addition to the study to show bioequivalence between the pioneer and generic products, we may require you to conduct a palatability study with the generic product. Palatability is not directly related to effectiveness. Palatability studies may be required in an ANADA with regard to the change in dosage form under section 512(n)(1)(D) of the FFDCA. We recommend that you submit protocols for our evaluation before initiating any studies.

We will conduct a definitive labeling review when the ANADA for the proposed generic product is submitted to the Center. The generic labeling should be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences, such as directions for administration of the chewable tablet.

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FDA/CVM/ONADE

TEL: 301 594 2297

P. 003

SP 99P-5329/CP 1

Page 2

You may contact Dr. Lonnie W. Luther, Chief, Generic Animal Drug and Quality Assurance Staff, (301) 827-0209, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,

/s/

Claire M. Lathers, Ph.D., F.C.P.

Director

Office of New Animal Drug Evaluation

Center for Veterinary Medicine

MEMO

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

of pages 3

From <i>John Gurney</i>	From <i>S. HANSARD</i>
Dept./Agency <i>DOCKETS</i>	Phone # <i>827 0211</i>
Fax # <i>827-6870</i>	Fax #
NSN 7640-01-817-7389 5089-101 GENERAL SERVICES ADMINISTRATION	

DATE: 4/14/00

FROM: Animal Scientist
Quality Assurance Support Staff, HFV-102

SUBJECT: Suitability Petition Response for Display.

TO: Lyle Jaffe, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD
Dockets Management Branch, 301 827-6860 (V)

Replacement Copy per Telecon 4/14/00 Dockets Mgt Branch

The attachment is the Center for Veterinary Medicine's letter related to Suitability Petition **SP 99P-5329CP 1**, Shotwell & Carr filed as a **Suitability Petitions**. We are forwarding copies for public display with the petition.

If you have any questions, please call me at 827-0211, or FAX 594-2297.

Thank you.

Sam Hansard 04/14/00
Sam Hansard, Ph.D.

Attachment

Samuel Hansard, Ph.D.
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